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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/068,812	02/04/2002	Richard J. Greff	29985/05-117A	8436

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EXAMINER	
GHALI, ISIS A D	

ART UNIT	PAPER NUMBER
1611	

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08/18/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/068,812	GREFF, RICHARD J.	
	Examiner	Art Unit	
	Isis A. Ghali	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 June 2008* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *22-38 and 42* is/are pending in the application.

4a) Of the above claim(s) *34-38* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *22-33 and 42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The receipt is acknowledged of applicant's amendment and request for RCE, both filed 06/06/2008.

Claims 22-38, and 42 are pending. Claims 34-38 are withdrawn from further consideration as being directed to non-elected invention.

Claims 22-33 and 42 are included in the prosecution.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 06/06/2008 has been entered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

> art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 22-33, 42 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims as amended to recite: "continuous coating" has introduced new matter. Nowhere applicants disclosed "continuous coating". Applicants refer to the method of making, and relying on the fact that soaking of gelatin in the wetting agent followed by drying resulted into continuous coating. However, nowhere applicants had showed the gelatin is continuously coated with the wetting agent as evident by claim 22 itself that recites: "coating on at least substantial portion of the surface of gelatin". Therefore, the coating is only on a portion of the surface of the gelatin sponge.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 22-33 and 42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are confusing because claim 22 recite two contradicting limitations that is "continuous coating" and "coating on at least substantial portion of the surface".

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 22-29, and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 02-182259 (259).

JP '259 teaches composition comprising cross linked gelatin, and solution comprising surfactant impregnated into the cross linked gelatin (see the provided abstract). The composition comprises 1-50 % of gelatin in aqueous solution and from 0.1 % to 30 % of the aqueous solution is the surfactant (page 5, last paragraph; page 6, first full paragraph). The reference disclosed in the process of making the composition,

the gelatin solution is prepared, then, the surfactant is added followed by foaming and drying, i.e. evaporation of the solvent (page 6, second full paragraph; page 10, operational example 1). The composition easily dissolves in blood or body fluids, i.e. bioabsorbable (page 7, third line). The surfactants disclosed by the reference include sodium lauric sulfuric acid, polyethylene glycol alkyl ether and sorbitan fatty acid ester (page 7, second full paragraph). The material disclosed by the reference that comprises cross-linked gelatin and the same wetting agent, is expected to decrease the hydration time of the cross-linked gelatin that claimed in claim 22. Furthermore, on page 5, lines 25-27 of the present disclosure, applicants disclosed that the hydration time is the time needed to prepare the gelatin for use, and the reference disclosed on page 11, third full paragraph that hemostatic composition showed slight swelling and arrested bleeding in 60 seconds, i.e. the composition was ready for use.

The difference between JP '259 and the present invention is that JP '259 does not explicitly teach coating of the wetting agent on the surface of the cross-linked gelatin. However, the reference disclosed soaking of gelatin sponge in solution wherein surfactant is added to this solution, page 6, lines 8-12. After drying the mixture of gelatin and the surfactant of the reference, it is expected to have some wetting agents on the surface of the product, which reads on partially coating. In any event, the presence of the wetting agent as a coating on the surface does not impart patentability of the claims, absent evidence to the contrary. No superior and unexpected results of record obtained by coating the wetting agent on the surface of the gelatin versus incorporating the wetting agent into the gelatin.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide composition comprising cross-linked gelatin sponge soaked in wetting agent as disclosed by JP '259, and it is expected to have the wetting agent on the surface of the product after drying as a partial coating.

Response to Arguments

9. Applicant's arguments filed 06/06/2008 have been fully considered but they are not persuasive. Applicants argue that Yasushi teaches the hemostatic plaster is formed by: (1) forming an aqueous gelatin solution; (2) adding a surfactant to the gelatin solution; (3) stirring the solution to form foam and freeze-drying the foam to obtain a gelatin sponge; and (4) soaking the sponge in an organic solvent solution containing a cross- linking agent. Applicant argue that Yasushi does not teach or suggest the soaking of a gelatin sponge in a surfactant solution and therefore does not teach the coating of a surfactant or wetting agent on the gelatin sponge. Further applicants argue that Yasushi's surfactant is not coated on the surface of the gelatin sponge because the surfactant does not form a continuous layer over the gelatin sponge. Yasushi's surfactant is evenly impregnated throughout the gelatin sponge. Although a small portion of Yasushi's surfactant may be present on the surface of the gelatin sponge, it still cannot form a continuous layer thereon as required by the definition of "coating". As a result, one of ordinary skill in the art would not consider Yasushi's surfactant as a "coating" or "'partial coating". Yasushi fails to disclose each element of the claims.

In response to this argument, applicants' attention is directed to the scope of claims 22-29 and 42 that is directed to composition comprising crosslinked gelatin sponge and wetting agent coating substantial portion of the gelatin sponge, and Yasushi teaches crosslinked gelatin foam impregnated with the wetting agent, and applicants themselves admit that a small portion of Yasushi's surfactant may be present on the surface of the gelatin sponge, and this reads on "coating on a substantial portion of the surface is coated with wetting agent". In absence of definition of "continuous coating of at least a substantial portion of the surface of the gelatin" the disclosure of the reference reads on the claims. It is further argued that the present claims are directed to product, and the elements of the product as disclosed by the reference, and the method of the reference does not impart patentability to the product claims and patentability is determined by the product itself. The reference method provides crosslinked gelatin foam impregnated with same wetting agent claimed by applicants, therefore, having some wetting agent on the surface of the gelatin foam.

10. Claims 30, 32, and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP '259 in view of US 6,603,061 ('061).

The teachings of JP '259 are discussed above. However, JP '259 does not teach that the composition is sterilized and packaged as claimed by claim 30, or the composition comprising thrombus enhancing agent as claimed in claim 32, or antimicrobial agent as claimed in claim 33.

US '061 teaches a biocompatible hemostatic composition comprising non-hydrated cross-linked gelatin, plasticizer and hydrating agent (col.3, lines 4-6, 43, 67; col.4, lines 11-12, 41-42; col.5, line 40; col.8). The composition further comprises active agent such as antibiotics and hemostatic agents including thrombin and clotting factors (col.11, lines 16-35). The composition can be in the form of sterile package (col.3, lines 33-34; col.5, lines 6-10, 25-35; col.8, lines 32-36).

Therefore, it would have been obvious to one having ordinary skill in the art at he time of the invention to provide the hemostatic composition disclosed by JP '259 and add antimicrobial and/or clotting factors as disclosed by US '061, motivated by the teaching of US '061 that such agents are beneficial for hemostasis, with reasonable expectation of having hemostatic composition comprises cross-linked gelatin and wetting agent and further comprises antimicrobial and/or clotting factors that are beneficial for hemostasis. Additionally, one having ordinary skill in the art would have been motivated to sterilize and package the gelatin sponge produced by JP '259 as disclosed by US '061, motivated by the logic of the wound dressing art that sterilization and package of gelatin material will be safer to use on the wound or bleeding site, with reasonable expectation of having sterile packaged gelatin sponge incorporating wetting agent that is safe to apply to bleeding site or wound.

11. Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over JP '259 in view of EP 5568 334 ('334).

The teachings of JP '259 are discussed above. However, JP '259 does not teach that the composition comprising growth factor as instantly claimed claim 31.

EP '334 teaches collagen containing sponge comprising cross linked gelatin and active agent, preferably growth factors which enhanced wound healing and nerve regeneration (abstract; col.5, lines 22-30).

Therefore, it would have been obvious to one having ordinary skill in the art at he time of the invention to provide hemostatic composition comprising cross linked gelatin and wetting agent as disclosed by JP '259, and add growth factors to the composition as disclosed by EP '334, motivated by the teaching of US '334 that growth factors are preferred active ingredient to be added to hemostatic gelatin wound treating composition because growth factors enhance wound healing and nerve regeneration, with reasonable expectation of having composition comprising cross linked gelatin, wetting agent and growth factors wherein the composition enhances wound healing and nerve regeneration successfully.

Response to Arguments

12. Applicant's arguments filed 06/06/2008 have been fully considered but they are not persuasive. Applicants traverse the rejection of claims 30 and 32-33 over Yasushi in view of Wallace (US '061); and the rejection of claim 31 over Yasushi in view of Song (EP '334) by arguing that the deficiencies of Yasushi are not addressed by Wallace nor Song and they do not teaches or suggests a surfactant or wetting agent forms continuous coating on the surface of a gelatin sponge.

In response to theses argument, applicants' attention is directed to the scope of the present claims that are directed to product and the elements of the product are disclosed by Yasushi in absence of definition of "continuous coating on at least a substantial portion of the surface of the gelatin sponge", as set forth in section 9 of this office action. Wallace is relied upon for the solely teaching that active hemostatic agents can be incorporated into wound dressing, and for teaching the packaging. Song is relied upon for the solely teaching of benefit of growth factor to the wound. It has been held that "When a patent simply arranges old elements with each performing the same function it had been known to perform and yields no more than one would expect from such an arrangement, the combination is obvious." *KSR Int 'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1740 (2007) (quoting *Sakraida v. AG Pro, Inc.*, 425 U.S. 273,282 (1976)). "When the question is whether a patent claiming the combination of elements of prior art is obvious," the relevant question is "whether the improvement is more than the predictable use of prior art elements according to their established functions."

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on (571) 272-0614. The fax phone

number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

IG

/Isis A Ghali/
Primary Examiner, Art Unit 1611